UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14-cv-01614-AJT-JFA Hon. Anthony J. Trenga Hon. John F. Anderson
JANINE ALI, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14cv-01615-AJT-JFA Hon. Anthony J. Trenga Hon. John F. Anderson

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT'S MOTION TO STRIKE PUNITIVE DAMAGES DEMAND

Plaintiffs Janine Ali and Gilda Hagan-Brown each demand punitive and exemplary damages for their claims against Defendant Eli Lilly and Company ("Lilly"). Lilly has moved separately for summary judgment for each of the claims on which Plaintiffs' demand is based, which if granted will render Plaintiffs' demand moot. But even if some aspect of Plaintiffs' claims survives, Plaintiffs cannot clear the high bar required for punitive damages. The Court should accordingly strike Plaintiffs' demand.

Punitive damages are permissible only where there is "misconduct or actual malice, or such recklessness or negligence as to evince a conscious disregard of the rights of another."[1] *Simbeck, Inc. v. Dodd Sisk Whitlock Corp.*, 508 S.E.2d 601, 604 (Va. 1999). They are not favored and "should be awarded only in cases involving the most egregious conduct." *Bowers v. Westvaco Corp.*, 419 S.E.2d 661, 668 (Va. 1992). As the Virginia Supreme Court has noted, "[p]laintiff's proof requires evidence of 'actual or constructive consciousness that injury will result from the act done or omitted.'" *Green v. Ingram*, 608 S.E.2d 917, 924 (Va. 2005).

In particular, courts both in Virginia and around the nation have held that punitive damages are not available as a matter of law where a manufacturer warns of the potential risk that resulted in the plaintiff's injury, even though that warning might subsequently be determined to be inadequate. *See Dudley v. Bungee Int'l Mfg. Corp.*, No. 95-1204, 1996 WL 36977, at *3 (4th Cir. Jan. 31, 1996) ("[S]ince [defendant] warned of the potential danger that injured [plaintiff], it exhibited some care for his safety. Because [defendant] exercised some care for the safety of others, an award of punitive damages was not warranted under a failure to warn theory."); *see also Heston v. Taser Int'l, Inc.*, 431 F. App'x 586, 589 (9th Cir. 2011) (upholding a decision to vacate a punitive damages award where "TASER made efforts, albeit insufficiently, to warn its customers about the risks posed by prolonged TASER deployment"); *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1317 (11th. Cir. 2000) ("[T]he issue of punitive damages

[1] Lilly is headquartered in Indiana, which like Virginia has a cap on the amount of punitive damages available to plaintiffs: the statutory maximum for such awards is three times the amount of compensatory damages awarded or $50,000, whichever is greater. Ind. Code Ann. § 34-51-3-4 (West); Va. Code Ann. § 8.01-38.1 (West). Because there is no material difference between the two laws, the Court need not engage in a choice of law analysis but may instead apply the law of Virginia. *See Nossen v. Hoy*, 750 F. Supp. 740, 743 (E.D. Va. 1990) ("Because the laws of the two states do not conflict in a material way . . . this Court will proceed without directly addressing the choice of law question.").

should not go to the jury when a manufacturer takes steps to warn the plaintiff of the potential danger that injured him; such acts bar a finding of wantonness." (quoting *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1058 (11th Cir. 1994)) (Alabama law); *Bhagvandoss v. Beiersdorf, Inc.*, 723 S.W.2d 392, 398-99 (Mo. 1987) (en banc) (reversing a finding of punitive damages in a failure to warn case involving bandages, noting that "[i]nadequate communication cannot be equated to conscious disregard" of patient safety, and that "there is no showing that the appellant concealed anything from the FDA, or failed to cooperate.") (Missouri law) (cited by *Dudley*, 1996 WL 36977, at *3).

Punitive damages are therefore not appropriate here, where Lilly explicitly warned about the risk of Cymbalta discontinuation symptoms. It is undisputed that, since approval, the Cymbalta label has included a warning about the risk of discontinuation symptoms, a list of symptoms that occurred at or above a threshold frequency in clinical trials, and guidance on discontinuing the medication. Plaintiffs and their experts argue that Lilly should have described this risk differently in the Cymbalta label, but they cannot dispute that, since launch, the FDA-approved label for Cymbalta has contained a detailed, three-paragraph warning about the exact discontinuation symptoms alleged by Plaintiffs. Indeed, Plaintiffs' principal regulatory expert Louis Morris conceded, when considering the deficiencies that he alleged in Lilly's label, that he "[did] not have any -- any sense that they [Lilly] were trying to hide information." Deposition of Dr. Louis Morris, *Herrera / Hexum*, at 183:16-184:17 (Nov. 24, 2014), Ullman Decl. Ex. 1. And the Southern District of New York has already found the warning adequate as a matter of law, *see McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391 (S.D.N.Y. 2014)[2] -- indicating that it is in

[2] Two recent decisions in California have denied Lilly's motion for summary judgment on the basis of proximate cause. *See* Order Den. Def.'s Mot. for Summ. J., *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-2701, Dkt. 306 (C.D. Cal. June 19, 2015); Order Den. Def.'s Mot. for Summ. J., (continued…)

no way so deficient as to be considered malicious or to constitute conscious disregard for the rights of others.

Moreover, Plaintiffs rest their critique primarily on the data and conclusions presented in the publicly available Perahia article published by Lilly scientists, which in turn summarized the various clinical studies submitted to FDA and other regulators for the approval of Cymbalta.[3] *See* Compl. ¶ 82, *Ali*, Dkt. 1 (Nov. 26, 2014). The fact that this data was published shows that punitive damages would be inappropriate.

Finally, punitive damages are inappropriate where Lilly's warnings were developed in tandem with and approved by the FDA:

First, Cymbalta's label was based on full clinical trial data that was shared with the FDA, including numerous clinical trials that specifically measured DEAEs. *See* Complete Response to FDA Approvable Letter NDA 21-427, App. 9.2.9 (Mar. 24, 2003), CYM-00708136-8143 (providing consolidated DEAE data from six pre-approval clinical trials), Ullman Decl. Ex. 2; Reports of Analyses of Data from More than One Study for Cymbalta (Duloxetine hydrochloride) Chronic Pain tbls. 3.36 & 3.37 (May 12, 2009), CYM-00195110-5168 (providing consolidated DEAE data from a 48-study data set), Ullman Decl. Ex. 3.

Herrera v. Eli Lilly & Co., No. 2:13-cv-2702, Dkt. 306 (C.D. Cal. June 19, 2015). These decisions explicitly declined to reach adequacy and were based on the specific testimony of plaintiffs and prescribing physicians in those cases. They do not affect the Court's evaluation of whether Plaintiffs here are entitled to punitive damages.

[3] Plaintiffs also complain that Lilly did not use a "withdrawal symptom checklist" in conducting its clinical trials, which they allege renders those trials unreliable. *See* Compl., *Ali*, Dkt. 1, ¶ 82(d) (Nov. 26, 2014). This argument is merely a variation on a failure to test claim, which is not cognizable in Virginia. *See Ball v. Takeda Pharms. Am., Inc.*, 963 F. Supp. 2d 497, 506 (E.D. Va. 2013), *aff'd*, 584 F. App'x 78 (4th Cir. 2014); *Torkie-Tork v. Wyeth*, 757 F. Supp. 2d 567, 571-73 (E.D. Va. 2010); *Sykes v. Bayer Pharms. Corp.*, 548 F. Supp. 2d 208, 215 (E.D. Va. 2008).

Second, Lilly's warning uses the guidelines set forth by the FDA in constructing its content: the use of a threshold to identify symptoms in a label is consistent with FDA regulations and guidance directing that the label "list the adverse reactions identified in clinical trials that occurred at or above a specified rate appropriate to the safety database." 21 C.F.R. § 201.57(c)(7)(ii)(A) (2006); *see also* FDA, *Guidance for Industry: Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products–Content and Format* (Jan. 2006).

Third, the last two paragraphs of the discontinuation warning, which Plaintiffs complain are misleading because they refer to discontinuation events seen with the use of other antidepressants, were actually written and imposed by FDA as class labeling before Cymbalta even came on the market. *See* Letter from Russell Katz, M.D., Center for Drug Evaluation & Research, U.S. Food & Drug Admin., to Wyeth Pharmaceuticals Inc., at 4 (Mar. 19, 2004) ("Additionally, we are taking this opportunity, in a class labeling initiative for all of the selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs), to change labeling in regards to discontinuation symptoms . . . ."), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/020151_S032_EFFEXOR_TABLETS.pdf, Ullman Decl. Ex. 4. Numerous other antidepressants -- including Celexa, Effexor, Lexapro, Paxil, and Zoloft -- bear the same text in their labels. *See id.* (requiring the second and third paragraphs as mandated language in the Effexor label); Expert Report of Karen M. Becker, PhD ("Becker Report"), *Ali* / *Hagan-Brown*, at 19-20 (May 14, 2015) (citing FDA-approved labeling), Ullman Decl. Ex. 5.

Fourth, FDA reviewed and approved many revisions to the Cymbalta label, including to the discontinuation warning itself (changing the list of symptoms that reached the frequency

threshold, for example), without ever contesting the aspects of the warning that Plaintiffs now allege are inadequate. *See* U.S. Food & Drug Admin., Approval History NDA 021427, Cymbalta (listing Cymbalta labeling revisions), Ullman Decl. Ex. 6.

Punitive damages are intended to punish truly egregious conduct. As such, Virginia courts have *rejected* the imposition of punitive damages in situations far more egregious than even Plaintiffs' worst allegations in these cases: where a SWAT team member killed an innocent home visitor by shooting through a kitchen door, *see Green*, 608 S.E.2d 917; where a drunk driver committed a hit-and-run, leaving a bleeding victim at the scene of his crime, *see Doe v. Isaacs*, 579 S.E.2d 174 (Va. 2003); and where a pest control company applied a commercial pesticide to a residential home, resulting in injuries to the homeowners, and falsified documentation to cover it up, *see Kaltman v. All Am. Pest Control, Inc.*, 706 S.E.2d 864 (Va. 2011). In the situation presented here, where FDA approved (and repeatedly re-approved) the Cymbalta label based on Lilly's transparent sharing of clinical trial data with FDA, where the Cymbalta label contains an extensive warning about the precise risk alleged, and where Plaintiffs point to Lilly's own published article to support their claims, Plaintiffs cannot as a matter of law demonstrate that Lilly acted with the requisite level of malice or consciousness of injury to support a punitive damages award.[4]

[4] Plaintiffs, recognizing that Lilly's conduct comes nowhere near the standard necessary for an imposition of punitive damages, attempt to set forth a course of previous conduct by the company that they believe warrants punishment. *See* Compl. ¶ 88 (citing previous legal proceedings in 1985 and 2009). But punitive damages may not be awarded for injury to non-parties. *See Philip Morris USA v. Williams*, 549 U.S. 346, 353-355 (2007); *see also Ray v. Allergan, Inc.*, 863 F. Supp. 2d 552, 565 (E.D. Va. 2012). Plaintiffs have put forth no evidence that relates any of the conduct in this litigation to the drugs Oraflex or Zyprexa, nor are any of the parties injured by that conduct party to this litigation. Such allegations should therefore be disregarded.

For the foregoing reasons, Lilly respectfully requests that the Court strike Plaintiffs' demand for punitive damages.

Dated June 29, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 29th day of June, 2015, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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